

#23

Docket No. 01723326

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:

Jeffrey Owen Phillips

Serial No.: 09/481,207

Filed: January 11, 2000

For: Novel Substituted
Benzimidazole Dosage
Forms and Method of Using
Same

Examiner: Fan, J.

Group Art Unit: 1625

CERTIFICATE OF HAND-DELIVERY

I hereby certify that this paper or fee is being hand-delivered on the date indicated below to the U.S. Patent and Trademark Office, Washington, DC 20231

(typed or printed name)

(signature of person delivering paper or fee)

(Date)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

The following information is submitted pursuant to 37 CFR §§ 1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR § 1.56(a). This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§ 1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR § 1.56(a) exists.

Applicant submits herewith Form PTO 1449 listing the references cited in this Information Disclosure Statement. Applicant respectfully requests that the Examiner (1) initial each reference listed on the enclosed Form PTO 1449 indicating that the Examiner has

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considered and made those references of record in this application and (2) return a copy of the initialed Form PTO 1449 to Applicant.

Please note that this is Applicant's third Information Disclosure Statement submitted in this case.

Please also note that Applicant is submitting copies of references Nos. 64-65, 88, 99, 108-110, 114, 118, 120, 136, 139-142, 144-188, 191, 193-195, 200-201 and 205-207. Copies of these references were missing from the Information Disclosure Statement submitted on July 11, 2001. The Applicant respectfully requests the Examiner to place these references into the tabbed notebooks submitted to the Examiner on July 11, 2001.

Applicant is also in the process of obtaining reference Nos. 64 & 88 of the July 11, 2001 Information Disclosure Statement that will be supplied in the next several weeks. Full copies of reference Nos. 132, 143, 196 are not available and reference 200 is a duplicate of reference 188.

All references are being hand-delivered to the Examiner per her request.

REMARKS

Additionally, Applicant provides the following information for the Examiner's consideration. None of such information is believed to be material to the patentability of any pending claim herein. Nevertheless, the information is provided in the interest of completeness.

In about 1990, inventor Jeffrey O. Phillips first used "Simplified Omeprazole Solution" (SOS) experimentally in 5 patients at the University of Missouri Hospital. The SOS referenced throughout these Remarks was prepared by mixing enteric coated omeprazole granules 20 mg (Prilosec®) with 10 ml of 8.4% sodium bicarbonate solution and allowing the enteric coating to dissolve before oral or nasogastric tube administration. Such use was experimental and not a

public use of SOS, and SOS was not sold commercially at that time. *See* MPEP §2133(e) (“If the use or sale was experimental, there is no bar under 35 USC 102(b).”).

In about 1991 or 1993, inventor Jeffrey O. Phillips used SOS experimentally in 2 patients at Sacred Heart Medical Center in Spokane, Washington. Such use was not a public use of SOS, and SOS was not sold commercially at that time.

In about 1993 to 1995, inventor Jeffrey O. Phillips used SOS experimentally in critical care patients at the University of Missouri Hospital. Such use was not a public use of SOS, and SOS was not sold commercially during that time.

In October 1993 and in 1994, inventor Jeffrey O. Phillips discussed the possibility of performing a multicenter experimental study using SOS with the “Pharmacotherapy Working Group,” a group of 19 scientists. Such discussions do not constitute a public use of SOS as Dr. Phillips believed that such discussions were confidential, and they were for experimental purposes only.

In 1994 and 1995, inventor Jeffrey O. Phillips recalls that about 2 scientists contacted him after seeing his 1994 abstract mentioning SOS (Tab 112 of IDS sets filed in this case), and asked him how to make SOS. The scientists indicated to Dr. Phillips an interest in performing research on SOS at their institutions. Dr. Phillips provided them with the requested information for that purpose.

Reference No. 413 is a copy of a poster presentation presented in January 1994 by inventor Jeffrey O. Phillips and Michael Metzler of the University of Missouri at the Society for Critical Care Medicine Annual Meeting. This poster related solely to SOS, which was used in the study described in the poster. The poster did not disclose how to make the SOS. Both Drs.

obvious

Phillips and Metzler believe that they did not disclose how to make SOS to participants at the Annual Meeting.

Reference No. 414 is a copy of a Power Point presentation given on June 11, 1994 by inventor Jeffrey O. Phillips, entitled "Stress-related Mucosal Damage Optimizing Drug Therapy in the 1990's," to the University of Missouri Surgical Society at the University of Missouri. Dr. Phillips did not disclose how to make SOS during this presentation.

Reference No. 415 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 1996, entitled "Update on Acid-related Disorders – Optimizing Pharmacotherapy for the 1990's." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 416 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 1997, entitled "Stress-related Mucosal Damage – Optimizing Drug Therapy." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 417 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 1998, entitled "From Efficacy to Effectiveness Alternative Dosing of PPI's." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 418 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 1998, entitled "Simplified Omeprazole Suspension." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 419 is a copy of a Power Point presentation by Michael Metzler, MD, Department of Surgery, University of Missouri-Columbia given in 1999, entitled "Advances in the Use of PPI's from Efficacy to Effectiveness." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 420 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 1999 and 2000, entitled "Overview of Omeprazole Suspension – Problems with Administering Granules." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 421 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 2000, entitled "Overview of Omeprazole Suspension." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

Reference No. 422 is a copy of a Power Point presentation given by inventor Jeffrey O. Phillips to various groups in 2001, entitled "Stress Ulcer Prophylaxis in the 21st Century." Such presentation is not prior art because, among other things, it was given after the January 4, 1996 filing date of the provisional application to which priority is claimed herein.

This Information Disclosure Statement is being filed before the mailing date of a final Office Action or an action that closes prosecution or a notice of allowance. Accordingly, Applicant encloses the fee of \$180.00 required under 37 CFR § 1.17(p). Should there be any additional fees required, the Commissioner is authorized to charge Deposit Account No. 13-0019.

Should the Examiner have any questions regarding the foregoing, she is encouraged to contact the undersigned.

Respectfully submitted,

THE CURATORS OF THE
UNIVERSITY OF MISSOURI

By: MAYER, BROWN & PLATT

By: Joseph A. Mahoney
Joseph A. Mahoney (Reg. No. 38,956)

Dated: December 20, 2001

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(Date)

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Enclosed herewith is the Supplemental Information Disclosure Statement for the above-captioned case.

Also enclosed are:

1. Supplemental Information Disclosure Statement;
2. PTO Form 1449;
3. One (1) copy of 89 references, including a copy of each U.S. and foreign patent, and each publication or that portion of the publication which caused it to be listed;
4. One (1) copy of the full articles that are to be placed in the original disclosure notebooks in place of the abstracts under the tab numbers: 65, 99, 108-110, 114, 118, 120, 136, 139-142, 144-188, 191, 193-195, 200-201 and 205-207;
5. Supplemental Amendment and attached articles as follows:

- (i) Chi-Kong, *et al.*, Antacids Indications and Limitation, Drugs 47 (2), 305-317, 1994;
- (ii) P. Jungnickel, Pantoprazole: A New Proton Pump Inhibitor, Clinical Therapeutics, Vol. 22, No. 11, 1268-1293, 2000.
- (iii) G. Larson, *et al.*, Gastric Response to Severe Head Injury, The American Journal of Surgery, Vol. 47, 97-105, January 1984.
- (iv) P. Roy, *et al.*, Zollinger-Ellison Syndrome Clinical Presentation in 261 Patients, Medicine, Vol. 79, No. 6, 379-411, 2000.

6. Check in the amount of \$180; and

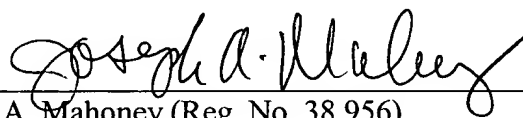
7. Return-receipt postcard.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019. A duplicate copy of this Transmittal Letter is enclosed.

Respectfully submitted,

THE CURATORS OF UNIVERSITY OF MISSOURI

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By: 
Joseph A. Mahoney (Reg. No. 38,956)

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